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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,620	11/27/2001	Amechand Boodhoo	8702.0001.03	5369

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,620	BOODHOO ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,27-31,37-41,47-51,57-61,67-71,77-81,87-89 and 96-99* is/are pending in the application.

4a) Of the above claim(s) *8-10,13-15 and 96-99* is/are withdrawn from consideration.

5)☒ Claim(s) *20,21,27-31,37-41,47-51,57-60,67-71,77-81 and 87-89* is/are allowed.

6)☒ Claim(s) *1-7,11,12,16-19 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 22-26, 32-36, 42-46, 52-56, 62-66, 72-76, 82-86 and 90-95 have been canceled. Claims 1-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81, 87-89 and 96-99 are at issue and are present for examination.

Claims 8-10, 13-15, and 96-99 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 4/30/03.

This application contains claims 8-10, 13-15, and 96-99 drawn to an invention nonelected with traverse in the reply filed on 4/30/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims. It is particularly noted that Claim 1 recites an amino acid sequence not present in the sequence listing.

Claims 3 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing as reciting a composition comprising a fragment of a full-length mocarhagin protein which is outside the scope of Claims 1 from which Claim 3 depends. Claim 1 as amended recites a composition comprising a mature mocarhagin protein and as such is limited to full length proteins.

Claim 61 depends from Claim 60 but recites a composition comprising the protein of SEQ ID NO:12 which is outside the scope of Claim 60. Claim 60 recites compositions comprising the protein of SEQ ID NO: 14 or specific fragments thereof. As SEQ ID NO:12 is different from SEQ ID NO: 14, this claim is confusing and improperly dependent and/or duplicative of Claim 51. It should be noted that Claim 60 appears to have a typographical error in part (d) in which fragments of SEQ ID NO:12 are recited. It is presumed this was intended to recite fragments of SEQ ID NO:14.

Claims 1-7 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (from which claims 2-7 and 16-19 depend) recites an N-terminal amino acid sequence not supported by the specification as filed. This is a new matter rejection.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 recites a composition comprising a mature mocarhagin protein at least 95% free of other cobra proteins and comprising the N-terminal amino acid sequence of SEQ ID NO:2. However, the specification fails to teach a single representative species of a mocarhagin protein comprising the recited sequence. Note none of SEQ ID NOS: 6, 8, 10, 12, 14, 16, or 18 comprise SEQ ID NO:2. Furthermore, the specification does not identify any cobra species from which such a protein can be isolated. Given this lack of description of representative species encompassed by the genus of the claim,

the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim 18 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mocarhagin proteins comprising residues 192-621 of SEQ ID NO:8, 192-439 of SEQ ID NO:8, 192-613 of SEQ ID NO:10, 192-521 of SEQ ID NO:12, 192-592 of SEQ ID NO:14, 62-462 of SEQ ID NO:16, or 197-621 of SEQ ID NO:18, fragments thereof having mocarhagin activity or mocarhagin isolated by the process of Example 1 of the specification, does not reasonably provide enablement for any mocarhagin polypeptide comprising SEQ ID NO:2 as an N-terminal amino acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The rejection was fully explained in the previous Office action. As previously noted Claim 18 recites an N-terminal sequence not present within any of the disclosed mocarhagin polypeptides, the specification fails to teach any particular cobra species which produces a mocarhagin protein with the

recited characteristics and it is unclear if any mocarhagin polypeptide (i.e., naturally occurring cobra venom polypeptide) having this N-terminal sequence even exists. Applicants failed to respond to this portion of the previous rejection so it is maintained for the reasons of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berndt et al. (US Patent 5,659,018) or De Luca et al.

This rejection as it applied to claims 1-2, 4-7, and 16-19 has been withdrawn in view of the amendment to Claim 1 to recite a N-terminal amino acid sequence that differs from the N-terminal amino acid sequence recited for the mocarhagin

composition taught by Berndt et al. As none of the amino acids sequences of SEQ ID NOS:6, 8, 10, 12, 14, 16, and 18 include the N-terminal sequence of Berndt et al. the rejection of Claims 20, 21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81, and 87-89 is withdrawn as well. Although DeLuca et al. do not recite an N-terminal amino acid sequence of the composition, the composition of DeLuca et al. was isolated by the exactly identical purification procedure as that of Berndt et al. and thus appears to be identical therewith. However, it is maintained as applied to Claims 11 and 12. With regard to Claims 11 and 12, applicants argue that claims 11-12 recite a product by process in which the process includes a final mono S column purification step. Neither cited reference recites this step (as the Office admits) and thus neither reference anticipates the claimed invention. This is not persuasive because the claim is to the product **not** to the method. The patentability of a product-by-process claim is determined by the characteristics of the **product** and not by the process steps. Unless the additional mono S purification step would exclude the mocarhagin proteins of Berndt et al. and DeLuca et al., the mocarhagin proteins of Berndt et al. and DeLuca et al. anticipate the instant claims. There is no reason to believe that this would be the case in

view of the high similarity between the mocarhagin proteins of Berndt et al. and DeLuca et al. and those disclosed in the instant application. Each of the preparations was isolated from the venom of the same species of cobra by purification methods which differ only in the addition of the mono S step of the instant application and the proteins isolated are clearly highly homologous as the N-terminal sequence has 79-83% identity with the N-terminal sequences of SEQ ID NOS:6, 8, 10, 12, 14, 16, and 18 and have identical functional properties. As such there is no reason to believe the mono S column would exclude the proteins of Berndt et al. and DeLuca et al. and thus these proteins anticipate the instant claims. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art compositions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art compositions does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Note while the protein of Berndt et al. and DeLuca et al. is clearly distinct from the proteins of SEQ ID

NOS:6, 8, 10, 12, 14, 16, and 18, the current product-by-process claims appear to be broad enough to encompass all of these distinct proteins.

With regard to the alternative 103 rejection applicants argue that it would not be obvious to specifically add an additional mono S column to the purification of Berndt et al. and De Luca et al. However, it is not necessary for the examiner to show that selection of a mono S column would have been obvious to one of skill in the art in order to further purify the mocarhagin composition but merely to show it would have been obvious to further purify to achieve the same level of purification as the claimed process achieves as patentability of a product in product-by-process claims is determined only by the characteristics of the product produced not by the process itself. As such any product with the same level of purity and function as produced by the claimed process regardless of the similarity of the method of producing it to that recited in the claim would meet the instant claim. As many means of further purifying the mocarhagin composition are known and could be used the product as claimed remains obvious.

Claims 20,21,27-31,37-41,47-51,57-60,67-71,77-81 and 87-89 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty

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